

JUN 26 2002

10014281

Munktell Filter AB
Box 300
S 790 20, Grycksbo, Sweden

Non-Confidential Summary of Safety and Effectiveness

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April 15, 2002

Munktell Filter AB
Box 300
S 790 20 Grycksbo, Sweden

Tel - 011 (46) 23-683-80
Fax - 011 (46) 23-401-15

Official Contact: Gustav Kyrk – Managing Director

Proprietary or Trade Name: Gard Filter

Common/Usual Name: Bacterial / Viral Filter

Classification Name: Filter, Bacterial, Breathing Circuit

Predicate Devices: Mallinckrodt Sterivent (HEPA) – K941676
ARC Filter – K011212
Porous Media – DBF 23 – K964979

Device Description:

The Munktell Gard Filter is a machine-side filter and incorporate standard 15 / 22 mm connectors. The depth filter uses a pleated paper fiber for filtration.

Intended Use:

Indicated Use -- For use with ventilators, anesthesia machines, and open flow systems where filtration of inspired and / or expired gases is desired. To be placed at the machine-side of the circuit only. Intended for single patient use up to 24 hours.

Environment of Use -- Home, Hospital, Sub-acute Institutions

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General Technical Characteristics

Attribute	Munktell – Proposed devices
Indications for use - To filter inspired and / or expired gases	Same
Intended for single patient use, up to 24 hours	Yes
Prescription	Yes
Intended population	Any patient (adult)
Intended Environment of Use	Home, Hospital, Sub-acute institutions
Placement at machine side of circuit only	Yes
Design	
Gas sampling port	Yes
Standard 15/22 mm connectors	Yes
Dead Space (ml)	124 ml
Resistance to flow	≤ 1.6 cm H ₂ O @ 60 lpm
Bacterial filtration – BFE – Nelson Lab.	99.9999%
Viral filtration – VFE – Nelson Lab.	99.9999%
Weight (gm)	60 gm
Materials	
Housing polystyrene	Yes
Filter media	Paper microfiber
Performance Standards	
None under Section 514	Yes
ISO 5356-1 Conical 15/22	Yes

Differences between Other Legally Marketed Predicate Devices

The data within the submission demonstrates that the proposed devices when compared to the predicate devices are safe and effective and are substantially equivalent to the predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 26 2002

Munktell Filter AB
c/o Mr. Paul Dryden
ProMedic, Inc.
6329 W. Waterview Court
McCordsville, IN 46055

Re: K014281
Gard Filter, Model # 321 111
Regulation Number: 868.5260
Regulation Name: Breathing Circuit Filter
Regulatory Class: II (two)
Product Code: 73 CAH
Dated: April 2, 2002
Received: April 3, 2002

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

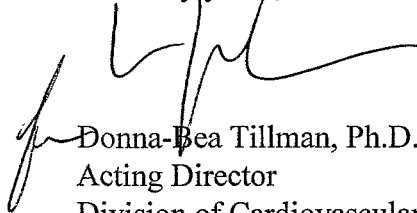
Page 2 - Mr. Paul Dryden

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Donna-Bea Tillman", is written over the typed name.

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

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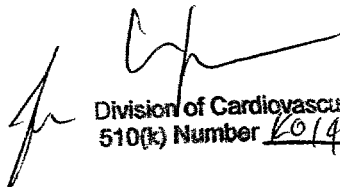
510(k) Number: K014281

Device Name: Gard Filter

Intended Use: For use with ventilators, anesthesia machines, and open flow systems where filtration of inspired and / or expired gases is desired. To be placed at the machine –side of the circuit only.

Single patient use. Duration of use up to 24 hours.

Concurrence of CDRH, Office of Device Evaluation (ODE)


Division of Cardiovascular & Respiratory Devices
510(k) Number K014281

Prescription Use ____
(Per CFR 801.109)

or

Over-the-counter use ____